JUL 12 2002

K021927

Summary of Safety and Effectiveness

PCCS Platelet Concentrate Separation Kit

Applicant/Sponsor: Biomet, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, IN 46581-0587

Contact Person: Lonnie Witham
Phone: (574) 267-6639
Fax: (574) 372-1683

Trade Name: Platelet Concentrate Separation Kit

Common name: Centrifuge accessories

Classification Name: Centrifuges (micro, ultra, refrigerated) for clinical use – accessory kit

Legally Marketed Devices to Which substantial Equivalence is Claimed:
The modified device is substantially equivalent to the original Implant Innovations CelSep® Centrifuge System (K994148) for producing platelet rich plasma from 50-60 ml of whole blood.

Device Description
The platelet concentrate separation kit aids separation of the patient's own blood components by density through the use of a centrifuge. The platelet concentration kit permits platelet rich plasma to be rapidly prepared from a small volume of the patient blood that is drawn at the time of treatment.

Kit Components: 18 gauge x 1" x 12" apheresis needle, 16 gauge centesis needle 1 ¼" catheter, 60 ml piston syringe, 30 ml piston syringe, 1 ml piston syringe, petri dish, rubber tubing tourniquet, gauze pad, alcohol pad, adhesive tape, silicone tube, volume gauge, PETG tray with sealed Tyvek® lid

Intended Use:
The Platelet Concentrate Separation kit is designed for use in the clinical laboratory or intra-operatively at point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60 ml) of whole blood.

Summary of Technologies:
The device has the same technological features as other tabletop centrifuge systems previously cleared by the FDA via the 510(k) process. This kit consists of standard legally marketed devices including syringes, needles, gauze, adhesive tape, alcohol pad, rubber tubing tourniquet, petri dish, and centrifuge blood processing disposable container used to draw and process a small sample of whole blood. The blood is spun in a centrifuge to produce platelet rich plasma. The centrifuge system has similar technological features as the predicate device cleared in K994841.

Non-Clinical Testing:
Laboratory testing was performed to compare the efficiency of the modified device with the predicate device in producing platelet rich concentrate. A functional test was performed on bovine and human blood and the platelet count results verified that the modified device produced platelet rich plasma at a concentration that was equal to or greater than the predicate device.

Clinical Testing: Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Lonnie Witham
Biomet, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581-0587

Re: k021927
Trade/Device Name: Platelet Concentrate Separation Kit
Regulation Number: 21 CFR § 862.2050 and 21 CFR § 880.5860
Regulation Name: General Purpose Laboratory Equipment and Piston syringes
Regulatory Class: I and II
Product Code: LXG and FMF
Dated: June 11, 2002
Received: June 12, 2002

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K021927

Device Name: Platelet Concentrate Separation Kit for CelSep® Centrifuge System

Indications for Use:
The Platelet Concentrate Separation kit is designed for use in the clinical laboratory or intra-operatively at point of care, for the safe and effective preparation of platelet poor plasma and platelet concentrate from a small sample (50-60 ml) of whole blood.

The plasma and concentrated platelets can be used for diagnostic tests.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Janette M. Clark FOR J. BAUTISTA

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 021927